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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Rolf C. Hagen Inc.

Serial No.:

10/685,685

Filed:

October 15, 2003
TOPICAL GEL MATRIX

For:

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Examiner:

Eric E. Silvermann

DECLARATION UNDER 37 CFR 1.132

Dear Sir:

- I, Benoît Choquet, B. Sc., declare as follows:
- I, Benoît Choquet, residing at 762 Bourbonnais Ave., Vaudreuil, Quebec, Canada, am a person of skill in the art of the above-mentioned application. I have obtained my Bachelor of Science degree in 2001 from McGill University, in the field of Agriculture. I have worked as a Research Associate at Rolf C. Hagen Inc. since 2001.
- 2. Rolf C. Hagen Inc. is a worldwide manufacturer and distributor of pet supply products.
- I am one of the inventors of the gel matrix for topical use as described and claimed in the above-identified patent application.
- I have followed the prosecution of this case and have read, in particular, the Final Office Action mailed by the United States Patent and Trademark Office on August 16, 2007.

- 5. I understand that the Examiner is not satisfied with the fact that a viscosity ranging between about 35 and 55 centipoises (CPS) can be obtained with the claimed amount of about 15% w/w Aculyn44 (polyethylene glycol-150/decy alcohol/saturated dicyclohexy-methane diisocyanate copolymer), in combination with the claimed ranges of other ingredients.
- I have ordered to a technician at Rolf C. Hagen Inc. that some experiments be done to provide evidence representative of the entire ranges of claimed ingredients.

Empirical experiments

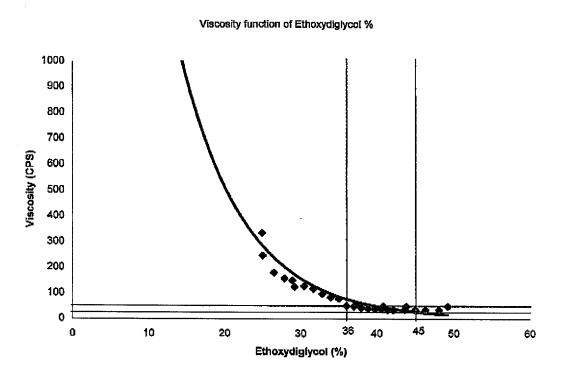
- 7. The experiments I ordered may be briefly summarized as follows: mix about 15% w/w Aculyn44 with various relative amounts of ethoxydiglycol in the presence of demineralized water, mix until a homogeneous liquid gel is obtained and then measure viscosity. The viscosity was measured with a Brookfield LVF viscosimeter.
- 8. In these experiments, I chose to include the ingredients which, to my knowledge, significantly contribute to the viscosity before application of the gel matrix as defined in the claims of the above-identified application, namely water, ethoxydiglycol and Aculyn44.
- 9. By doing a simple parallel with the working example given in the application as filed (pages 9-11, paragraphs [0029]-[0035]), water is representative of Part A, ethoxydiglycol is representative of Part B and Aculyn44 constitutes Part C.

10. The experiments, done in October 2007, resulted in test points 1-22 in Table 1 below, with a relative amount of ethoxydiglycol varying from 25.00 to 48.08% w/w.

Table 1			
Test points	Ethoxydiglycol	Viscosity	
	(% w/w)	(centipoises)	
1	0	16300	
2	25.00	247.5	
3	26.46	180	
4	27.86	157.5	
5	29.19	125	
6	30.45	127.5	
7	31.66	117.5	
8	32.83	97.5	
9	33.94	82.5	
10	35.00	77.5	
11	36.02	50	
12	37.00	47.5	
13	37.94	42.5	
14	38.85	40	
15	39.72	37.5	
16	40.55	37.5	
17	41.36	35	
18	42.14	34.5	
19	43.62	35.5	
20	45.00	35	
21	46.29	35	
22	48.08	35	

11. The graph below represents the viscosity as a function of the relative amount of ethoxydiglycol in the mixture, including all values of Table 1 (with the sole exception of the viscosity of 16300 CPS when no ethoxydiglycol is present).

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- 12. In addition to the above experiments, I have done another empirical experiment in June 2007, based on the working example given in the application as filed (pages 9-11, paragraphs [0029]-[0035]), wherein some ingredients of Part B were substituted with water. More specifically, the following four (4) mixtures were made:
- 13. Mixture 1: complete Tropical Matrix Mixture (Parts A, B and C) as described in the example of the application;
- 14. Mixture 2: complete Parts A and C, but in Part B Sweet Birch Extract was substituted with water;
- 15. Mixture 3: complete Parts A and C, but in Part B ethoxydiglycol was substituted with water; and
- 16. Mixture 4: complete Parts A and C, but part B was substituted with water.

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17. The viscosity of each mixture was then measured (in CPS), and the results are given in the table below.

1	2	3	4
51	53	16300	5150

Analysis of the results

- 18. The results of the October 2007 experiment presented above clearly demonstrate that a viscosity comprised between about 35 and about 55 CPS, i.e. within the claimed viscosity range, may be obtained in a composition containing about 15% w/w Aculyn44, in the presence of 36.02% w/w (about 36%) to at least about 45% w/w ethoxydiglycol.
- 19. I note that, in the experiment of June 2007, ethoxydiglycol is present at a level of 37.4% w/w in Mixtures 1 and 2 and that the viscosities of both mixtures are consistent with the results obtained in October 2007.
- 20.1 also note that the experiment of June 2007 allows to confirm that the presence of the surfactant (in this experiment, 3% w/w) with ethoxydiglycol in Part B (*Mixture 2*) does not significantly contribute to the viscosity of the gel matrix before application.
- 21. These two experiments together thus confirm that a gel matrix comprising about 15% w/w Aculyn44, as well as ethoxydiglycol and a polysorbate surfactant in ranges as defined in amended claim 1, allows obtaining a viscosity between about 35 and about 55 CPS.
- 22.1 note that the ranges of ethoxydiglycol given in the application as filed were 32%-45% w/w (see paragraph [0029]) or 34-45% w/w (see paragraph [0034]) and I confirm that we were in good faith when providing these original ranges.

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23. It however appears that the results above are clearly representative of a slightly more limited range of about 36% to about 45% w/w ethoxydiglycol.

Conclusion

- 24. In my opinion therefore, the topical gel matrix as defined in amended claim 1, with a range of about 36% to about 45% w/w ethoxydiglycol, would clearly enable a person of ordinary skill in the art to reproduce the claimed gel matrix without undue experimentation and obtain the desired viscosity.
- 25. In my opinion, the evidence provided herein is commensurate with the ranges of ingredients as defined in the claims.
- 26. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilful false statements and the like made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States. Code and that such wilful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Respectfully submitted,

Data

29 Otdou 2007

Benoît Choquet